REMARKS/ARGUMENTS

Claims 1, 9-16, 18-24, 33-36 and 38-40 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Pat. No. 6,129,756 to Kugler in view of U.S. Pub. No. 2003/0236567 to Elliot. Claims 2-7 and 37 are rejected under 35 U.S.C. § 103(a) over Kugler in view of Elliot and in further view of U.S. Pat. No. 6,168,621 to Vrba. Applicants respectfully submit that the above claims are allowable for at least the following reasons.

I. REJECTIONS UNDER 35 U.S.C. § 103

With regard to rejections under 35 U.S.C. § 103, the Examiner must provide evidence which as a whole shows that the legal determination sought to be proved (*i.e.*, the reference teachings establish a *prima facie* case of obviousness) is more probable than not. M.P.E.P. § 2142. Accordingly, "the key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." M.P.E.P. § 2142; *see KSR International Co. v. Teleflex, Inc.*, 550 U.S.398, 82 U.S.P.Q. 2d 1385, 1395-97 (2007).

When rejecting the claims based on a combination of prior art elements according to known methods to yield predictable results, as the Office Action does in the present instance, the Office Action must articulate four factual findings. M.P.E.P. § 2143(A). First, there must be "a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference." *Id.* Second, there must be "a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately." *Id.* Third, there must be "a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable." *Id.* Fourth, there must be articulation of "whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under

consideration, to explain a conclusion of obviousness." *Id.* For the following reasons, Applicants respectfully submit that the pending claims are allowable at least because the cited references, either in combination or individually, do not teach all elements of the claims or obvious variations thereof.

1. Independent Claim 1

As amended, claim 1 recites "A stent-graft device for treating an abdominal aortic aneurysm, the stent-graft device" that comprises:

> at least one stent member comprising at least one of a self-expanding stent member and a balloon-expandable stent member;
>
> at least one tubular graft member coupled with the at least one stent member, the tubular graft member having a proximal end and at least one distal end, said at least one tubular graft member, once deployed, comprising a main graft member toward the proximal end of the tubular graft member and at least one sinusoidal leg member, each of said at least one sinusoidal leg member being coupled with the main graft member at its proximal end and extending toward the distal end of the tubular graft member; and
>
> at least one skirt graft member coupled with at least one of the stent member and the tubular graft member at or near the proximal end of the tubular graft member and extending toward the distal end,
>
> wherein the skirt graft member is configured to be placed in contact with the inner wall of the aortic aneurysm when the stent-graft device is implanted adjacent to the abdominal aortic aneurysm.

In particular, Applicants have amended claim 1 to incorporate subject matter from claims 9 and 11, namely, to specify that, upon deployment, "at least one tubular graft member" comprises "a main graft member toward the proximal end of the tubular graft member and at least one sinusoidal leg member, each of said at least one sinusoidal leg member being coupled with the main graft member at its proximal end and extending toward the distal end of the tubular graft member." Applicants respectfully note that the Office Action does not address the sinusoidal leg members, as recited in claim 11 prior to the present amendment, and, therefore, has not made a *prima facie* case of obviousness with respect to claims that incorporate such subject matter. Nevertheless, Applicants respectfully submit that the aforementioned element of

amended claim 1 is indeed allowable under 35 U.S.C. § 103 at least because the cited references, individually or in combination, do not disclose, teach, or suggest this element and for additional reasons.

For instance, the Office Action on page 4 acknowledges that the primary reference Kugler does not teach a graft member that has two sinusoidal members that are helically intertwined, but does not otherwise address sinusoidal leg members in general. With respect to leg members being helically intertwined, the Office Action asserts that it would have been obvious to one of ordinary skill in the art to modify the shape of the corrugated portions of leg members of Kugler to form a helical shape because "it has been held that changing the shape of a working part involves only routine skill in the art." The Office Action cites *In re Dailey*, 357 F.2d 669, 149, U.S.P.Q. 47 (C.C.P.A. 1966) for this proposition. Assuming for the sake of argument that, had the Office Action addressed general sinusoidal leg members, the Office Action's rationale would have been similar, Applicants respectfully disagree.

In *Dailey*, the court held that the claimed change in shape of a baby bottle was obvious because there was no argument "that the particular configuration of [applicant's] container is significant or is anything more than one of numerous configurations a person of ordinary skill in the art would find obvious." *Id.* at 50. Unlike the device in Dailey, in the present instance, Applicants' sinusoidal leg member provides significant advantages over prior art devices.

For example, as noted in Applicants' specification at page 16, paragraph 63, a sinusoidal leg portion includes bends that allow a stent-graft device to straighten and/or bend in one or more directions to absorb length changes to which the stent-graft device is subjected and thus reduce stress/strain on the stent-graft device. Further noted in the same paragraph, generally, sinusoidal graft portions or legs provide long-term elasticity and also provide relatively laminar flow, without causing dramatic atherosclerotic response within the graft due to turbulence or shear. Thus, Applicants' stent-graft device, as recited in claim 1, has a permanent ability to elongate as the patient moves and provides a smooth and continuous flow path to

minimize shear on the blood and maintain laminar flow with minimal turbulence or stagnant pockets where thrombus may be generated.

The bellows in Kugler, on the other hand, as best understood by Applicants, do not provide these advantages. For example, as best understood by Applicants, the bellows of Kugler allow elongation at the time of deployment in order to make the graft a suitable length, but do not retain the ability to elongate after they have been deployed in order to accommodate movement of the patient. *See* Kugler, FIG. 9; column 15, lines 23-38. In fact, Kugler actually teaches away from elongation of a stent-graft device subsequent to deployment because gripping stents are used that "serve to straighten the bellows region of the graft, and to prevent them from further elongation after deployment of the system." *Id*. Applicants note that, looking to FIG. 9b of Kugler, Kugler's device would have to be elongated in order to attain a sinusoidal shape. Therefore, because Kugler teaches away from post-deployment elongation of a leg portion, Kugler also teaches away from a stent-graft device having sinusoidal leg portions.

Moreover, the bellows in Kugler additionally do not provide a continuous flow path that minimizes shear on the blood and that maintains laminar flow with minimal turbulence or stagnant pockets where thrombus may be generated. Indeed, looking at FIGS. 2-3, 5, 7-13 which show Kugler's bellows as forming a wall comprising a series of parallel, closely-spaced jagged angles and not a smooth contour that would have the aforementioned advantages of Applicants' sinusoidal shape. Even assuming arguendo that the bellows design of Kugler provides adequate movement, the bellows design still does not provide a smooth channel through which fluid can pass without unnecessary turbulence and/or stagnant pockets.

Applicants respectfully note that the secondary reference, Elliot, does not make up for Kugler's failure to teach Applicants' non-obvious sinusoidal leg portions. For instance, Elliot's figures do not disclose, teach, or suggest sinusoidal leg portions, but at most a graft having a straight portion that curves slightly at one end. *See* Elliot, Fig. 1.

Accordingly, in light of the significant advantages provided by Applicants' stent-graft device having at least one sinusoidal leg member, Applicants respectfully submit that the subject matter of claim 1 is not merely a combination of prior art elements where one element is

recited to be a mere change in shape, as in *Dailey*, but allowable under 35 U.S.C. § 103 over Kugler in view of Elliot. Accordingly, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 103 be withdrawn.

2. Independent Claims 33

Applicants respectfully submit that amended claim 33 is allowable under 35 U.S.C. § 103 over Kugler in view of Elliot at least for reasons similar to those discussed above in connection with claim 1. For example, amended claim 33 recites "at least one graft member coupled with and extending between the proximal stent member and the at least one distal stent member, at least a portion of the graft member, upon deployment, having a sinusoidal shape." For at least reasons similar to those discussed above, Applicants respectfully submit that Kugler and Elliot do not, either individually or in combination, disclose, teach, or suggest at least this element.

3. Dependent Claims 2-8, 10-16, 18-24 and 34-40

Claims 2-8, 10-16, 18-24 and 34-40 depend from one of claims 1 or 33 and, therefore, Applicants respectfully submit that claims 2-8, 10-16, 18-24 and 34-40 are allowable at least for depending from an allowable base claim. In addition, Applicants respectfully submit that at least some of claims 2-8, 10-16, 18-24 and 34-40 are patentable because they further define subject matter that is not disclosed, taught or suggested by the prior art. For example, claim 12 recites that "the two sinusoidal leg members are helically intertwined." As discussed above, the Office Action alleges that this element recites only a change of shape of a working part that involves only routine skill in the art. For reasons similar to those discussed above in connection with the sinusoidal shape, Applicants respectfully submit that the helical shape of claim 12 is not an obvious variation of a prior art device and, in fact, for reasons discussed above, Kugler teaches away from the helical shape, which provides at least the above-discussed advantages over Kugler's bellows device with respect to elongation and smooth flow.

In addition to the foregoing, Applicants appreciate withdrawal the species election. While Applicants respectfully disagree with the basis for withdrawal, Applicants

believe that the species election is moot because, as discussed above there is an allowable generic claim.

II. NEW CLAIMS 55-69

Claims 55-69 are new and supported by the originally filed application. Applicants respectfully submit that claims 55-69 recite features that are not disclosed, taught, or suggested, either individually or in combination, by Kugler, Elliot, and Vrba. For example, independent claim 55 recites "at least one stent member comprising a plurality of expandable members coupled together circumferentially to form a cylinder, some of the expandable members comprising a self-expanding material and others of the expandable members comprising a balloon-expandable material." Applicants respectfully submit that Kugler, Elliot, and Vrba do not, individually or in combination, disclose, teach, or suggest this element.

As acknowledged in the Office Action at page 5, the modified device comprising teachings of Kugler and Elliot does not disclose a stent member comprising both a self-expanding stent member and a balloon-expandable stent member. The Office Action notes that Vrba teaches that self-expanding stent members and balloon-expanding stent members can be arranged in alternating sequences and cites to Vrba at column 2, lines 50-55, which refers to Figure 6 of Vrba. Applicants respectfully note that Figure 6 of Vrba shows a balloon-expandable part 14 between two self-expanding parts 12. Thus, each cylindrical section of the stent of Vrba comprises either a balloon-expandable material or a self-expanding material, but does not comprise both self-expanding and balloon expandable members as claimed in claim 55. Vrba's self-expanding sections are joined to balloon expandable sections axially, not circumferentially as recited in claim 55.

As noted in Applicants' specification at paragraph 49, Applicants' device as claimed in claim 55 has advantages over prior art devices. For example, Applicants' claimed combination "may provide for a conveniently self-expanding stent which could be further expanded by a balloon, to attach securely to the wall of the aorta and prevent leakage of blood around the device." Vrba's device, on the other hand does not function in the same manner.

Referring to Vrba's Fig. 6, as best understood by Applicants, Vrba's stent self-expands at the ends until the middle is expanded with a balloon whereas Applicants' alternating members allow the middle portion to self-expand and be further expanded by a balloon.

As another example, claim 61 recites "at least one stent member comprising at least one of a self-expanding stent layer and a balloon-expandable stent layer, the self-expanding stent layer and balloon-expandable stent layer being laminated to one another." Applicants respectfully submit that such subject matter as recited in claim 61 is not disclosed, taught, or suggested, either individually or in combination, by Kugler, Elliot, and Vrba. Further, Applicants respectfully submit that the stent member of Applicants' device, as recited in claim 61, has at least the aforementioned advantages over Vrba's stent.

As yet another example, claim 56 recites "the at least one stent member has a first end portion, a second end portion, and a middle portion between the first end portion and second end portion, and wherein the plurality of expandable members are disposed in the middle portion." As noted above, a combination of Kugler and Elliot do not disclose, teach, or suggest this element and Vrba shows a balloon-expandable part 14 between two self-expanding parts 12. Applicants' claim 56, on the other hand, recites the middle portion as comprising alternating self-expanding and balloon-expandable members. For reasons discussed above, Vrba's middle portion does not function as the middle portion recited in claim 56, which provides advantages over the prior art.

III. AMENDMENTS TO THE CLAIMS

Unless otherwise specified or addressed in the remarks section, amendments to the claims are made for purposes of clarity, and are not intended to alter the scope of the claims or limit any equivalents thereof. The amendments are supported by the specification and do not add new matter. In addition, by focusing on specific claims and claim elements in the discussion above, Applicants do not imply that other claim elements are disclosed or suggested by the references. In addition, any characterizations of claims and/or cited art are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a

later date any other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by another prosecution. Accordingly, reviewers of this or any child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present disclosure.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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